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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/529,166 | 08/08/2005 | Christoph Burkhart | PD/4-32516A | 4328 |

1095 7590 06/29/2006

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

| EXAMINER | |
|---|---|
| SINGH, ANOOP KUMAR | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1632 | |

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/529,166 | BURKHART ET AL. | |
| | Examiner | Art Unit | |
| | Anoop Singh | 1632 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-10 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-10 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

1. Claims 1-10 are under consideration.

### *Election/Restrictions*

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3, 6 and 7, drawn to a kit and a method for the determination of a T-cell and/or inflammatory effector cell derived mediator directly *in vivo* in serum, comprising a mouse wherein the majority of T cells express a transgenic MHC class I restricted or MHC class II restricted T cell receptor.

Group II, claim 4, 5 and 8, drawn to a method for identifying an agent and using said agent that interferes with T cell activation and/or -differentiation and/or modulation of other inflammatory effector cells.

Group III, claim(s) 9-10, drawn to method for the treatment of a disease which is based on an unwanted or aberrant immune response, comprising administering an agent identified to interferes with T cell activation and/or -differentiation and/or modulation of other inflammatory effector cells.

3. The inventions listed as Groups I do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

4. The technical feature linking the inventions of groups I-III is a mouse wherein the majority of T cells express a transgenic MHC class I restricted or MHC class II restricted T cell receptor. Knott et al (Am J Respir Crit Care Med. 2000; 161(4 Pt 1): 1340-8) teach a Homozygous, naive $\alpha\beta$-TCR transgenic Balb/c that are sensitized to OVA. Knott discloses that at various times after aerosol exposure mice are euthanized and bronchoalveolar lavage (BAL) is performed on their lungs. Knott also teach measuring IgE in serum to determine if there was significant humoral immunity present in serum. Thus, it would be obvious for a skilled artisan to take the mouse disclose by the Knott and use a OVA peptide or triggering agent and then measure humoral response by measuring IgE in serum. Therefore, the instant technical feature of Groups I-III does not make a contribution over prior art.

The technical feature of group I is a Kit comprising a mouse wherein the majority of T cell express a transgenic MHC class I which is distinct and different from inventions of groups II-III, which are drawn to distinct method and composition that do not share the same inventive concept as group I. The invention of Group II recite a method of identifying an agent and using that agent intended for therapy while group III is drawn to a method of treatment, these methods that do not share same inventive concept as in group I and are not required nor recited in the claimed invention of group I, and thus have their own technical feature e.g. kit comprising mouse (group I), identification of agent (group II), treatment of disease (group III).

5. Each invention is directed to distinct goal, which comprises the use of a mouse wherein majority of T cells express a transgenic MHC I restricted or MHC class II restricted T cell receptor in order to achieve its respective and intended objective. Thus, it follows from the preceding analysis that the claimed inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the reasons set forth above.

6. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner: Claim 10 is generic.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

Since each disclosed patently distinct species comprising unwanted or aberrant immune response is selected from the group consisting of allergic disease, transplantation, autoimmune related disease, inflammatory disease and modulation/stimulation of a tumor specific or pathogen specific response and complement do not share a substantially common structure and may have distinct mode of action. Thus, requirement of unity of invention is not fulfilled.

7. A search and examination of more than one invention as defined above would unduly burden the office. Each of the inventions requires a different search of the art and concerns separate considerations of patentability. For example, the subject matter of many of the subject matter of many of the inventions is not largely co-extensive as the inventions are related to distinct method and compositions. Therefore, restriction as defined above is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anoop Singh whose telephone number is (571) 272-3306. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272- 0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Anoop Singh, Ph.D.
Examiner, AU 1632